K082367
1 of 1

Life Innovations
Limited Liability Company

510(k) SUMMARY

JUN 12 2009

Submitter:	**Life Innovations, LLC.**
Address:	**P.O. Box 148** **Wellington, CO 80549**
Phone Number:	**(208) 316-5297**
Fax Number:	**(208) 734-9941**
Contact Person:	**Jane Y. Scott, M.D.** **Chief Executive Officer** **Jsco704@aol.com**
Date Prepared:	**June 10, 2009**
Device Trade or Proprietary Name:	**Infant Sleep Beanie**
Device Common or Usual Name:	**Pediatric position holder**
Classification:	**Division of Anesthesiology, General Hospital, Infection Control and Dental Devices** **Panel: General Hospital and Personal Use Devices** **Classification: Class I (reserved)** **Classification Code: FRP**
Predicate Device(s):	**Kozy Comfort™ Infant Positioner K062143** **Head Bed™ Infant Positioner K060986** **Robin Hood Vest™ K051300** **Nightform™ Infant Sleep Positioner K041996**
Device Description:	**The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel.**
Intended Use:	**The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.**
Technological Characteristics:	**The Infant Sleep Beanie is worn on the infant's head and therefore the infant is unable to roll or turn away from the repositioning aid. The Infant Sleep Beanie can be used in all locations – car seat, bouncer, crib, floor stroller, etc. It is a convenient product that is easy to pack and change if soiled.**
Performance Summary:	**The FDA has not established special controls or standards for this device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

Jane Y. Scott, M.D.
Chief Executive Officer
Life Innovations, LLC
P.O. Box 148
Wellington, Colorado 80549

Re: K082367
Trade/Device Name: Infant Sleep Beanie
Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: June 10, 2009
Received: June 10, 2009

Dear Dr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082367

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Prescription Use_____ **AND/OR** **Over-The-Counter Use**___X___
(Part 21 CFR §801 Subpart D) **(21 CFR §801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082367